

SPECIFICATION AMENDMENTS

Page 17, last paragraph continuing onto page 18:

In order to minimize contact between the suture and insertion tool during the insertion process, it is preferable to thread the suture through an accessory bore 36 having a diameter of preferably approximately 0.028 in. (0.7112 mm). The use of a separate accessory bore 36 for the suture reduces stress that may be put on the suture if threaded in anchor bore 34 alongside the insertion tool. Accessory bore 36 is preferably substantially perpendicular to anchor bore 34, as seen in the side views of suture anchors 322, 522 and 722 in FIGS. 4, 6, and 8, respectively. The location of accessory bore 36 is selected to have the smallest effect on the strength of the suture anchor because of the deficit of suture anchor material. One of ordinary skill in the art can determine, by routine experimentation and an analysis of the geometry of the suture anchor, the optimum point at which accessory bore 36 can be placed without detrimentally ~~effecting~~ affecting the strength of the suture anchor. The distance of accessory bore 36 from leading edge 30, along the axis of the suture anchor, is preferably between 0.15-0.20 in. (3.81-5.08 mm), and most preferably approximately 0.18 in. (4.572 mm) in suture anchors 20, 22, 322, and 722, and 0.16 in. (4.064 mm) in suture anchor 522.

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Insertion tool 40 41 of FIG. 9 has a substantially straight elongated body 42 ending with insertion end 44, which is inserted inside anchor bore 34 of the suture anchor. Bead 46 demarcates insertion end 44 from the remainder of body 42 and prevents body 42 from entering anchor bore 34. The diameter of insertion end 44 should be sufficiently wide to provide a secure fit inside anchor bore 34 of the suture anchor (also accounting for the amount of suture material, if any, inside anchor bore 34). The diameter of bead 46 should be substantially larger in diameter than anchor bore 34 in order to limit movement of insertion end 44 through anchor bore 34.

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Insertion tool 48 of FIG. 10 also has a substantially straight elongated body 50 ending at insertion end 52. Like insertion tool 40 41, insertion end 52 of insertion tool 48, is distinctly demarcated from the remainder of body 50 to thereby limit movement of body 50 through anchor bore 34. In this instance, insertion end 52 is narrower than body 50 and distinctly begins at step 54. Insertion end 52 must be sufficiently thick to form a secure fit within anchor bore 34 of the suture anchor during insertion into the patient bone hole (also accounting for the amount of suture material, if any, inside anchor bore 34). It will be appreciated that one or both sides of insertion tool 48 may be stepped.

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Insertion tools 40 41, 48, 56, and 56' may have a handle (not shown) at the end opposite insertion end 44, 52, 60 to facilitate gripping of the insertion tool during insertion of the suture anchor into the patient bone hole. Typically the hand grip would be wider and longer than body 42, 50, and 58.

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For reasons as will be described in connection with the method of insertion, at least insertion ends 44, 52, and 60 of insertion tools 40 41, 48, 56 and 56', respectively, should be formed from a material having elastic properties, preferably superelastic properties, such as a shape memory material. The elastic or superelastic properties of the material should be such that the insertion end is not substantially permanently deformed during insertion of the suture anchor and will substantially return the insertion end to an initial configuration (generally the configuration of the insertion end at the time it is initially mounted in anchor bore 34, prior to insertion of the suture anchor into the patient bone). The preferred material for at least the insertion end of the insertion tool is a nickel titanium alloy. Such materials are available commercially, under the names NITINOL™ or TINEL™ (RayChem) or SENTINOL™ (GAC International, Inc.). Such shape memory alloys having superelastic properties are well known in the art. See, e.g., United States Patent Nos. 4,505,767, and 4,565,589. However, any other shape retaining material sufficient for properly inserting the suture anchor of the present invention into a patient bone

hole may be used. See e.g., Shirai and Hayashi, (*Mitsubishi Technical Bulletin*) 184, pp. 1-6 (1988).

Page 22, first full paragraph:

As shown in FIG. 16, suture 64 is threaded through anchor bore 34, and suture anchor 20 is mounted on insertion end 44 of insertion tool 40 41. Insertion end 44 enters anchor bore 34 adjacent trailing edge 32 of suture anchor 20 and exits (if at all) adjacent leading edge 30. Because insertion end 44 of tool 40 41 is securely positioned within anchor bore 34, anchor bore 34 is not easily distinguishable, in the FIGS., from the outer surface of insertion end 44. Anchor bore 34 is preferably drilled parallel to base 28 such that force applied by the insertion tool advances the leading edge of the suture anchor toward the patient bone hole. Insertion tool 40 41 is positioned parallel to the longitudinal axis of patient bone hole 70, maintaining anchor bore 34 and base 28 (if anchor bore 34 is drilled parallel to base 28) parallel to patient bone hole 70, as well. Leading edge 30 of suture anchor 20 is positioned to be the first portion of suture anchor 20 to enter patient bone hole 70.

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Once the conical surface extending between leading edge 30 and apex 24 encounters patient bone hole 70, suture anchor 20 begins to rotate or reorient, as shown in FIG. 18, in order to fit into patient bone hole 70. Main body 42 of insertion tool 40

41 is maintained parallel to patient bone hole 70. Thus, when suture anchor 20 reorients, insertion end 44 bends.

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Typically, insertion end 44 is bent to the greatest extent immediately before trailing edge 32 leaves the portion of patient bone hole 70 in patient cortical bone tissue 74, as shown in FIG. 19. Once trailing edge 32 begins traveling through patient cancellous bone tissue 76, insertion end 44 begins to resume its initially straight configuration, as shown in FIGS. 20 and 21, thereby deploying the suture anchor. Preferably, main body 42 of insertion tool 40 41 is not as flexible as insertion end 44, and remains straight throughout the insertion procedure.

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Once apex 24 has cleared patient cortical bone tissue 74, and the entire suture anchor is in cancellous bone tissue 76, insertion end 44 of insertion tool 40 41 is able to return to its original configuration, as shown in FIG. 22. The pointed shape of apex 24 allows suture anchor 20 to more easily cut through cancellous bone tissue 76 so that the suture anchor may be reoriented and secured in its final position. As shown in FIG. 23, insertion tool 40 41 can then be disengaged from the suture anchor and removed. Pulling the suture anchor 64 up and away from patient bone 72 at this point may aid in dismounting the suture anchor from the insertion tool in addition to rotating and thereby properly seating suture anchor 20 in cancellous bone tissue 76. Preferably suture 64 is once again pulled up and away

from patient bone 72 after the insertion tool is removed to firmly position 35 suture anchor 20 in patient bone 72, preferably against the undersurface of cortical bone 74, within the transition region between cortical bone matter 74 and cancellous bone matter 76. Typically, suture 64 will be substantially centered within patient bone hole 70, and suture anchor 20 will be substantially horizontal. Suturing of body tissue to patient bone 72 can now be commenced.

Page 35, the Abstract:

A suture anchor having a conical surface and a bore in which an end of an insertion tool is inserted. The insertion end of the insertion tool is made of material having elastic properties. The bore and base of the suture anchor are angled with respect to the central axis of the suture anchor and preferably are parallel to each other. During insertion, the suture anchor is reoriented to fit into the hole, thereby bending the elastic end of the insertion tool. When the suture anchor is within cancellous bone tissue, the elastic properties of the insertion tool deploys the suture anchor to an orientation in which the suture anchor cannot fit through the bone hole, thereby firmly anchoring the suture anchor in the human bone.